



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1049]

Conditional Approval of New Animal Drugs; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting to explore the use of statutory changes to expand the use of conditional approval to additional categories of new animal drugs. This policy exploration is consistent with a stated performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter. FDA is requesting that you submit any comments related to this issue by September 30, 2015.

Date and Time: The public meeting will be held on March 16, 2015, from 1 p.m. until 4 p.m.

Location: The public meeting will be held at the Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., 3rd Floor, Rockville, MD 20855. Parking is free.

Contact Person: Laura Bradbard, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., rm. 159, Rockville, MD 20855, 240-276-9109, FAX: 240-276-9020, email: Laura.Bradbard@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this meeting must register by March 10, 2015. For general questions about the meeting, for assistance to register for the meeting, to request an opportunity to make an oral presentation, or to request special accommodations due to a disability, contact

Laura Bradbard (see Contact Person). Please include your name, organization, and contact information. If you are requesting an opportunity to speak, please send a brief summary of your comments. Early registration for the meeting is encouraged due to limited time and space.

SUPPLEMENTARY INFORMATION:

I. Background

FDA considers the timely review of the safety and effectiveness of new animal drugs to be central to the Agency's mission to protect and promote the public health. Before 2004, the timeliness and predictability of the new animal drug review program was a concern. The Animal Drug User Fee Act enacted in 2003 (Pub. L. 108-130; hereinafter referred to as "ADUFA I"), authorized FDA to collect user fees for 5 years--fiscal year (FY) 2004 to FY 2008--that were to be dedicated to expediting the review of new animal drug applications according to certain performance goals and to expand and modernize the new animal drug review program. The Agency agreed to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new animal drug application review process.

In 2008, before ADUFA I expired, Congress passed the Animal Drug User Fee Amendments of 2008 (Pub. L. 110-316; hereinafter referred to as "ADUFA II"), which included an extension of ADUFA for an additional 5 years--FY 2009 to FY 2013. ADUFA II performance goals were established based on ADUFA I FY 2008 review timeframes. In addition, FDA provided program enhancements to reduce review cycles and improve communications during reviews.

In 2013, before ADUFA II expired, Congress passed ADUFA III (Pub. L. 113-14), which was signed by the President on June 13, 2013. Like its predecessors, ADUFA III includes its own comprehensive set of performance goals. One such goal, as stated in the ADUFA III goals letter, is: Beginning in early FY 2014, the Agency agrees to explore, in concert with industry, the feasibility of pursuing statutory revisions, consistent with the Agency's mission to protect and promote the public health, that may expand the use of conditional approvals to other appropriate categories of new animal drug applications and develop recommendations by September 30, 2015.

Currently, the conditional approval provisions allow an applicant to market a new animal drug intended for a minor species or a minor use in a major species after the applicant has demonstrated that the drug is safe and can be manufactured according to standards applicable to approval of applications under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(1)). FDA and members of regulated industry jointly agreed to explore, as part of the performance goals outlined in the ADUFA III goals letter, statutory changes to expand the use of conditional approval to other appropriate categories of new animal drugs.

This public meeting is intended to provide an additional opportunity for public comment. The Agency is especially interested in receiving comments during the meeting on the categories of new animal drug applications that would be considered "appropriate" and why; concerns, if any, that might arise due to the expansion of the Conditional Approval process; and the length of marketing exclusivity, if any, that should be associated with the expansion of the Conditional Approval process.

FDA will consider comments received at this meeting as it moves forward with this process.

FDA has already opened public docket FDA Docket No. FDA-2014-N-1049 to receive comments on the issue (79 FR 53430, September 9, 2014). Although you can comment on this document at any time, to ensure that the Agency considers your comment before finalizing work on the exploration process described in this document, submit either electronic or written comments by September 30, 2015.

II. Participation in a Public Meeting

While oral presentations from specific individuals and organizations may be limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administration record (the docket). All relevant data and documentation should be submitted with the comments to Docket No. FDA-2014-N-1049. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number FDA-2014-N-1049. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meeting will become part of the administrative record. Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>, Docket No. FDA-2014-N-1049, and at FDA's CVM Web site at:

<http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm>. It

may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be recording the meeting via Adobe Connect on March 16, 2015. Once the recording has been made 508 compliant, it will be accessible at FDA's CVM Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm>.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.